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Typed Name: David W. Carthy
Date: November 10, 2008

Patent

0-05-037 (17551/US/04)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Sonnenschein
Serial no.: 10/526,845
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Submitted: March 3, 2005
Title: A STAPLING DEVICE
Examiner: Lindsay Low
Art Unit: 3721
Confirmation: 9356

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

Response and Amendment

This response is in reply to the office action mailed on August 27, 2008.

Applicant also encloses a change of address form.

Amendments to the Claims: The amended claims are similar to the claims amended under Article 34 PCT and annexed to the IPRP of the corresponding PCT application.

Amendment to the Specification: Attached is an amendment to page 9 of the specification to correct a typographical error as identified by the examiner. The applicant appreciates the examiner's thorough examination.

Drawings: Claim 8 has been cancelled thereby rendering the objection to the drawings moot.

Claim Rejections – 35 USC § 112: Applicant amends claim 1 to include the features of cancelled claims 3 and 4. It is felt that these amendments made to claim 1 overcome all of the rejections.

Claim Rejections – 35 USC § 103(a): The examiner rejected claims 1-7 and 9-10 as being unpatentable over Sonnenschein (2001/0056282 – henceforth D1) in view of Jankowski (2004/0004105 – henceforth D2) and claim 8 over the above references and further in view of Oberle (4,318,548).

The present invention:

The need for the present invention arose from the inventor's experience in developing and using the endoscopic stapler described in D1. Specifically it was discovered that, even with the help of an ultrasound positioning assembly, alignment of the components of the stapler such that the locking screws could be deployed was frequently a time consuming and tiring process for the operator.

The stapler described in D1 and the stapler of the present invention are unique in the art in that the two components of the stapler, *i.e.*, the staple containing and

firing part (cartridge) and the anvil are joined together by a flexible, articulation section. The practical result of this is that the legs of the staples will not curl against the anvil properly when the staples are fired unless the cartridge and anvil are rigidly joined together. The solution proposed by the inventors to the problem of joining the parts of the stapler together is to advance locking screws out of the anvil and to screw them into bores in the cartridge.

It is to be appreciated that the bores are very small, typically having a diameter on the order of 1mm. This, combined with the flexibility of the connection between anvil and cartridge and the fact that actual stapling is done inside body cavities, gives an indication of the nature of the difficulties involved in advancing the screws into the cartridge so that the stapling procedure can be carried out.

In order to properly align the anvil and the cartridge, such that the screws will enter the bores it must be possible to carry out the final alignment in both the longitudinal and the transverse directions simultaneously.

The prior art:

In all of the staplers described in D2 the staple containing and firing part of the stapler and the anvil are connected by a rigid connection, which acts as a centering base for alignment of the two parts of the stapler and allows the application of the required force during the stapling procedure. In the staplers shown in Fig. 1 and Fig. 6 of D2, the rigid connection is a pin about which the parts of the staple are pivoted relative to each other. In the staplers shown in Fig. 8 and Fig. 9 of D2, one of the elements is mounted on a rigid rod that is pulled longitudinally in order to bring the two parts of the stapler into contact when the staples are fired.

Surgical staplers of all of the types described in D2 are known and have been used in the art for many years. Applicant respectfully submits that, in properly designed staplers of these types, the presence of the rigid connection between the two parts of the stapler prevents misalignment between staples and anvil. In Applicant's view the curved surfaces taught in D2 are not necessary for alignment of the stapler parts, as stated by the inventor of D2, but they may be useful for other purposes, *e.g.*, for safely gathering, compressing, and gripping the tissue to be stapled.

D2 discloses two basic types of surgical staplers. Fig. 1 typifies the embodiments of linear stapler. Figs. 11-12 depict embodiments of circular staplers.

Patentability of the Claimed Invention:

The non-rigid connection between the two parts of the stapler of the present invention is the cause of the unique nature of the technical problem of aligning the anvil and cartridge in order to be able to connect them with screws to enable firing and proper closure of the staples. It does not seem reasonable, and certainly not obvious, for the inventors of the present invention to have turned to the prior art for the solution to a problem, which to their knowledge did not exist in the prior art (with the exception of D1) and that resulted from the radically different design of their stapler as compared to prior art staplers.

Specifically Applicant wishes to call attention to the fact that, despite the statement in paragraph [0006] of D2, in which the inventor identifies a need for providing a stapler with means for enhancing alignment of the anvil and cartridge in either the longitudinal or the transverse direction, there is no teaching in D2 of how to carry out the alignment simultaneously in both directions as is essential to the successful application of the present invention.

The examiner relies on D2 to supply the missing feature of the curved surfaces of the anvil and cartridge to the teachings of D1.

- a) With respect to the embodiments of linear stapler, D2 discloses curvature that aids alignment in one direction only; therefore the use of these embodiments of the staplers in D2 in combination with the stapler of D1 would not result in the stapler of the present invention.
- b) It could be argued that the circular staplers taught in D2 do result in two dimensional alignment of the anvil and staple cartridge. However, as pointed out by the Examiner in the IPRP of the PCT application parallel to the present one, "the person skilled in the art would not consider to use this arrangement [to solve the alignment problem of the present invention (added by Applicant)], because a circular row of staples does not make any sense in combination with the stapler of D1, which is intended for the therapy of GERD."

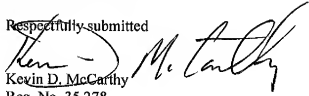
Neither D1 nor D2 teach a two level structure for the face of the cartridge similar in design or function to that taught in the present invention. The Examiner contends that D1 does teach a two level structure of the cartridge surface because of the fact that the holes for the locking screws have a bottom surface, which is below that of the surface at the top of the holes. The Examiner's remark is merely a play on words. It is difficult to take this argument seriously in view of the description and figures of the present application. Clearly the lower surface of the holes is not intended or capable of being the equivalent of the lower surface of the cartridge of the invention. Referring to Fig. 4, it is very clear what is meant by a two level structure for the surface of the cartridge. If the reasoning of the Examiner is to be followed, then instead of describing the cartridge in Fig. 4 as comprising two levels 50 and 52 it should be described as a three level structure, because of the presence of holes 46 or perhaps a four level structure because the slots 44 also have bottoms.

Conclusion:

The features of the present invention are not esthetic features but functional ones, i.e. the curvature of the cartridge and anvil surfaces in combination with the two level structure of the curved cartridge surface enable alignment to be simultaneously achieved in both longitudinal and transverse directions. The combination of D1 and D2 does not teach this combination of features. Therefore Applicant respectfully suggests that claim 1 and the claims dependent upon it are allowable.

It is respectfully submitted that the claims and application are in condition for allowance and it is earnestly solicited that such allowance be granted.

Respectfully submitted


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